Section 8 - 510(k) Summary

Date: 11 October 2013

Sponsor: Innovative Surgical Designs, Inc.
2660 E. 2nd Street #10
Bloomington, IN 47401
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OCT 17 2013

Contact Person: Ed Morris, CEO

Trade Names: True™ Spinal Fixation System

Device Classification Class II

Classification Name: Pedicle screw spinal system

Regulation: 888.3070

Device Product Code: MNI, MNH

Device Description: The True™ Spinal Fixation System consists of pairs of longitudinal members (rods), anchors (polyaxial pedicle screws) and interconnections (rod-rod connectors). These are available in a variety of sizes to accommodate differing patient anatomy. Dual Rod use Only. The True™ Spinal Fixation System is intended to be used only as a dual rod system and must be used with two rods per connector in all cases. Do not use one rod per connector.

Intended Use: The True™ Spinal Fixation System is intended for posterior, noncervical (T1-S1) pedicle fixation to provide immobilization and stabilization in skeletally mature patients as an adjunct to fusion for the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, spinal stenosis, scoliosis, kyphosis, lordosis, spinal tumor, pseudarthrosis and failed previous fusion.

Materials: True™ Spinal Fixation System implants are manufactured from titanium alloy (Ti-6Al-4V ELI) as described by ASTM F136. True™ Spinal Fixation System instruments are manufactured from 17-4 stainless steel ASTM F899 and IXEF PARA GS-1022.

Predicate Devices: CD HORIZON® (K031655/K041460), Moss® Miami (K992168/K022623) and the Synergy™ VLS (K950099/K974749)

Performance Data: Static compression bending and torsion, and dynamic compression bending tests were performed according to ASTM F1717 and ASTM 1798 on the worst case True™ construct. The mechanical test results demonstrate that the True™ Spinal Fixation System performance is substantially equivalent to the predicate devices.

Technological Characteristics: The True™ Spinal Fixation System possesses the same technological characteristics as the predicates. These include:

- basic design (rod-based pedicle screw fixation system),
- material (titanium alloy) and
- anatomic location.

Technological characteristics which are different have been supported with descriptive information and/or performance data which demonstrate the safety and effectiveness has not been diminished.

Conclusion: In comparison to the predicate devices, the True™ Spinal Fixation System has

- the same intended use (as described above),
- the same technological characteristics or different without raising safety and effectiveness issues (as described above)

Therefore the True™ Spinal Fixation System can be found substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 17, 2013

Innovative Surgical Designs, Incorporated
Mr. Ed Morris
CEO
2660 East 2nd Street #10
Bloomington, Indiana 47401

Re: K130958
Trade/Device Name: TRUE™ Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH
Dated: September 17, 2013
Received: September 19, 2013

Dear Mr. Morris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K130958

Device Name: **True™ Spinal Fixation System**

Indications for Use:
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Prescription Use __X__ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K130958